

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON**

UNITED STATES OF AMERICA,

Plaintiff,

v.

VARIOUS GOLD, SILVER AND COINS,
et al., *in rem*,

Defendants,

and

JAMES G. COLE, an individual,
JAMES G. COLE, INC., a corporation, and
SONIC LIFE.COM, LLC, formerly known
as **SONIC HEALTH SYSTEMS, LLC**, a
limited liability company,

Claimants.

Case No. 3:11-cv-01179-SI (Lead Case)
Case No. 3:11-cv-01424-SI

OPINION AND ORDER

S. Amanda Marshall, United States Attorney, Katherine C. Lorenz and Allan M. Garten, Assistant United States Attorneys, United States Attorney's Office, District of Oregon, 1000 S.W. Third Avenue, Portland, OR 97204. Of Attorneys for Plaintiff.

John J.E. Markham, II, MARKHAM & READ, One Commercial Warf West, Boston, MA 02110; Michael A. Cox, LAW OFFICE OF MICHAEL A. COX, 7420 S.W. Bridgeport Road, Suite 100, Tigard, OR 97224. Of Attorneys for Claimants.

Michael H. Simon, District Judge.

Plaintiff, the United States of America (the “Government”), brought this consolidated civil *in rem* forfeiture action against various items of property, referred to as “Defendants.” On November 13, 2013, after a seven-day trial, the jury rendered a verdict in favor of the Government. James G. Cole, James G. Cole, Inc., and Sonic Life.com, LLC (collectively “Claimants”) now move for a new trial under Federal Rule of Civil Procedure 59(a) (“Rule 59(a)"). Claimants challenge the jury’s verdict on two grounds. First, Claimants argue that the Court improperly excluded Claimant’s Trial Exhibit 261. Second, Claimants argue that the Court improperly admitted as “lay testimony” the testimony of Dr. Tom Brueggemeyer, which Claimants contend was actually “expert testimony.” For the reasons stated below, the Court DENIES Claimants’ motion for a new trial.

STANDARDS

A district court may grant a new trial “in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.” Fed. R. Civ. P. 59(a). In other words, a court may grant a new trial on “grounds that have been historically recognized.” *Zhang v. Am. Gem Seafoods, Inc.*, 339 F.3d 1020, 1035 (9th Cir. 2003). Historically recognized grounds include, but are not limited to, claims “that the verdict is against the weight of the evidence, that the damages are excessive, or that, for other reasons, the trial was not fair to the party moving.” *Molski v. M.J. Cable, Inc.*, 481 F.3d 724, 729 (9th Cir. 2007) (citing *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1940)). A “trial court may grant a new trial only if the verdict is contrary to the clear weight of the evidence, is based upon false or perjurious evidence, or to prevent a miscarriage of justice.” *Passantino v. Johnson & Johnson Consumer Prods.*, 212 F.3d 493, 510 n.15 (9th Cir. 2000).

Upon a Rule 59 motion by the party against whom a verdict has been returned, the district court has “the duty . . . to weigh the evidence as [the court] saw it, and to set aside the verdict of the jury, even though supported by substantial evidence, where, in [the court’s] conscientious opinion, the verdict is contrary to the clear weight of the evidence.” *Murphy v. City of Long Beach*, 914 F.2d 183, 187 (9th Cir. 1990) (quoting *Moist Cold Refrigerator Co. v. Lou Johnson Co.*, 249 F.2d 246, 256 (9th Cir. 1957)). Although a “trial court may weigh the evidence and credibility of the witnesses, the court is not justified in granting a new trial ‘merely because it might have come to a different result from that reached by the jury.’” *Roy v. Volkswagen of Am., Inc.*, 896 F.2d 1174, 1176 (9th Cir. 1990) (quoting *Wilhelm v. Associated Container Transp. (Austl.) Ltd.*, 648 F.2d 1197, 1198 (9th Cir. 1981)).

BACKGROUND

A. Maxam

Claimant James G. Cole (“Mr. Cole”) formed and operates James G. Cole, Inc., known by its trade names “Maxam Laboratories” and “Maxam Nutraceuticals” (collectively “Maxam”), in Hood River, Oregon. Maxam sells its custom-designed pharmaceutical supplements (“Maxam supplements”) as well as health supplements manufactured by other companies. The Maxam supplements were created and manufactured by Daniel George (“Mr. George”) in Massachusetts. Mr. George shipped what would become the Maxam supplements to Maxam in powdered form. Upon receipt of these powders, Maxam would rehydrate them with water. Maxam would then bottle, label, and sell the Maxam supplements to the public. Mr. Cole, who at times misrepresented that he was a naturopathic doctor despite not having a degree in the field or a registration with the American Association of Naturopathic Physicians, worked with Mr. George and Maxam employees to develop treatment protocols for the Maxam supplements targeted to

specific illnesses. For example, Maxam advertised and advised customers that various Maxam supplements could treat serious illnesses, such as autism, multiple sclerosis, and cancer.

The specific manufacturing processes used to create the Maxam supplements are known only to Mr. George. At trial, Mr. Cole described his general understanding of how the Maxam supplements are made. According to Mr. Cole, Maxam authorized Mr. George to order, on behalf of Maxam, custom compounds and products from J-Star Laboratories (“J-Star”), a company specializing in the creation of custom chemical compounds. After Mr. George ordered the J-Star compounds, J-Star would ship the compounds to Maxam in Oregon. Maxam inventoried the shipment, paid J-Star, and then re-shipped the J-Star compounds to Mr. George in Massachusetts. Mr. Cole also explained at trial that he believed that after Mr. George received the J-Star compounds, he would create a “primordial soup or broth” by combining the custom compounds with bacteria. The bacteria would then generate a polypeptide or “protective agent.” Mr. George allegedly harvested these peptides and used them to create Maxam supplements. Mr. Cole represented to the public that Mr. George was a Harvard-trained biochemist and therefore qualified to develop the treatment protocols advertised and recommended by Maxam. At trial, the primary evidence of Mr. George’s connection to Harvard University was the fact that he possessed a Harvard library card. Before beginning his work with Maxam, Mr. George was criminally convicted in 1984 for violating federal laws governing controlled substances.

B. Pretrial

During the discovery phase of this civil lawsuit, the Government responded to Claimants’ interrogatories requesting the disclosure of the Government’s theory of fraud related to the sale of Maxam supplements. The Government’s theory of the case expanded after the August 6, 2013 deposition of Dr. Andrew Thompson from J-Star. At that deposition, Dr. Thompson explained that at the direction of Mr. Cole, Dr. Thompson had not produced all of the documents

subpoenaed by the Government in December 2011. These documents related to products ordered by Mr. George for the manufacturing of Maxam supplements. Thompson Dep. Tr. at 89:7-17, 130:23-137:18, ECF 94-6 at 22-23, 33-35. At Mr. Cole's deposition on August 16, 2013, Mr. Cole admitted that Mr. George used the J-Star compounds in manufacturing Maxam supplements. Cole Dep. Tr. at 9:2-14:18, ECF 153-3 at 4, 5.

On September 6, 2013, the Government provided a Supplemental Response to Claimants' Document Request and Interrogatories, including six additional alleged misstatements and omissions concerning Mr. George and his manufacturing processes for Maxam supplements. Pl.'s Supp. Resp., ECF 153-1 at 3-5. Two of these theories are particularly relevant to the pending motion: (1) "Claimants failed to disclose that the Maxam products were manufactured by Mr. George using custom compounds from J-Star laboratory that were not intended for use in humans"; and (2) "Claimants failed to disclose that they allowed a convicted felon to order custom compounds from J-Star laboratory; that Claimants paid for and forwarded these custom compounds to Mr. George; that these custom compounds included prescription Monoamine Oxidase Inhibitors (MAOIs), prescription Selective Serotonin Reuptake Inhibitors (SSRIs), the prescription drug Selegiline used for Parkinson's disease which metabolizes in the body to methamphetamine, amphetamine and ephedrine, analogs [*sic*] of the above, and a substance with a chemical structure similar to MDMA or ecstasy; and that these custom compounds were used by Mr. George in his undisclosed location to create the Maxam product." *Id.* at 4-5.

Also on September 6, 2013, the Government timely provided the expert report of Dr. Cory Hilmas. Dr. Hilmas is Chief of the Dietary Supplement Regulations Implementation Branch, Division of Dietary Supplement Programs, at the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration ("FDA"). Dr. Hilmas's expert report

disclosed the list of J-Star compounds ordered and used by Mr. George, including the analogues¹ of ecstasy and other prescription medications. Claimants' Ex. I, ECF 149-9 at 2. Dr. Hilmas opined that there was "no scientific reason or basis" to use J-Star compounds, including prescription drugs and drugs that were not manufactured according to applicable regulatory standards, to create the "primordial soup or broth" that Mr. Cole claimed was the basis for Maxam supplements. *Id.* at 8. Dr. Hilmas further opined in his expert report that given the "paucity of details about the manufacturing process," the J-Star compounds

used in the broth are included in the final Maxam product, likely at very low levels that are below the detection limit of the screening methods FDA used in their analysis of the products. There was no description about how peptides could be isolated from the broth but how [J-Star] compounds and bacteria would be left behind. That would be supported by the fact that FCC was unable to detect [J-Star] compounds in Maxam products, but micro was able to grow unusual bacteria from the products. It is likely that there would not be any pharmacological effect given the low quantities of [J-Star] compounds synthesized for inclusion in the "broth" as well as the fact that FCC's screening methods were unable to detect any. If there were any pharmacological effect from the use of the [J-Star] compounds in the manufacturing process, it would have been constantly changing over the years. Maxam claimed to have had 400 unique fermentations involving 'special microbes' in their marketing materials.

Id.

Before trial, Claimants objected to portions of Dr. Hilmas's opinion. Claimants argued that this opinion went beyond an opinion based upon scientific expertise. Claimants did not, however, object to Dr. Hilmas's qualifications or ability to discuss the scientific basis and limits of the FDA testing of the Maxam samples. *See* ECF 121 at 20-22.

¹ As used in this opinion, the term "analogue" refers to a substance that has a substantially similar chemical structure to a known drug or controlled substance. A more specific definition of "analogue" is used in the federal Controlled Substance Analogue Enforcement Act of 1986, 21 U.S.C. § 802(32)(A)(i)-(iii).

Claimants also timely raised a pretrial objection to the admission of the purported “lay testimony” of Dr. Tom Brueggemeyer. Dr. Brueggemeyer is the Supervisory Chemist at the FDA’s Forensic Chemistry Center (“FCC”). Dr. Brueggemeyer was the person responsible for supervising the FCC’s testing of Maxam supplements. These test results were admitted as Trial Exhibits 11 through 16. The Government disclosed in its Lay Witness List Dr. Brueggemeyer’s involvement in the FDA’s investigation and testing of Maxam supplements, specifically:

Dr. Brueggemeyer will testify as to the FCC’s role in testing the Maxam products in response to requests received from Agent Rickher. He will describe the gas chromatography with mass spectrometric detection analysis (GC-MS) that was performed on certain of the Maxam samples, including its limitations. He will explain that samples are dissolved in a solvent, injected into the instrument, vaporized, and then swept by flowing helium gas into a long, thin column where the components of the sample separate from each other. He will explain that upon exiting this column, these components are fragmented and ionized, and that based on this pattern of fragments, the analyst can identify the molecules of interest by comparing them to commercial digital libraries of previously analyzed compounds. He will explain what constitutes a “match” between those libraries and sample compounds. He will explain that if a match is found, it is possible to confirm its identity by analyzing the pure chemical standard material under the same conditions.

Pl.’s Lay Witness List, ECF 92 at 18. The Government also disclosed that Dr. Brueggemeyer would explain the limitations in the tests that he oversaw as a part of his role at the FCC:

He will also explain that GC-MS it [*sic*] is not able to detect everything in the product, and he will explain what the FCC’s lab reports mean when they indicate that “no drugs or poisons” were found in samples using this test. He will testify that the GC-MS analysis is unable to detect non-volatile components including most inorganic substances such as salts; larger molecules such as proteins; and some drugs. He will also testify that there is no one single technique capable of detecting every component (including controlled substances, active pharmaceuticals, and analogs [*sic*] of those substances) of an unknown sample.

Id.

Claimants argued that Dr. Brueggemeyer’s testimony “clearly qualifies as expert testimony within the meaning of Rule 702.” Claimants’ Objections to Pl.’s Evidence, ECF 102 at 9. The Government responded by arguing that Dr. Brueggemeyer was offered “as a fact witness, and not as an expert.” Pl.’s Resp. to Claimants’ Objections, ECF 110 at 10. The Government further stated:

The subjects that Claimants complain would qualify as expert testimony for Dr. Brueggemeyer—including his explanation of the gas chromatography test used by the FDA in testing the Maxam samples sent by Agent Ricker and the inability of that test to detect all components in the product—are the very same subjects that Claimants’ counsel asked Dr. Brzezinski about during her deposition, and which she was unable to answer. *See* CR 107 (Claimants’ deposition designations for Dr. Brzezinski) at 10, 13, 22, and 24 (asking Dr. Brzezinski what a gas chromatography test is, how reliable the test is, what it looks for, and the test’s detection limits, and designating each of Dr. Brzezinski’s negative responses to be read to the jury). Moreover, Dr. Brzezinski mentioned Dr. Brueggemeyer during her deposition (*see Id.* at 40), and his signature appears on the FDA lab reports Plaintiff has offered and to which Claimants have indicated they have no objection as to the [*sic*] admissibility. Claimants could have noticed Dr. Brueggemeyer’s deposition during discovery if they had wished, but they did not. Dr. Brueggemeyer is not being asked to share any expert opinions, and he is no more an expert than Dr. Brzezinski was when Claimants took her deposition or designated her deposition testimony to be read at trial. Plaintiff asks that the Court overrule Claimants’ objections to his testimony so that he may answer the very fact questions about the test used on the Maxam samples that Dr. Brzezinski could not.

Id. at 10-11.

At the pretrial conference, the Court overruled Claimants’ objections, but added that if “Claimants have not previously taken the deposition of Dr. Brueggemeyer in this action and now wish to do so, the Government shall make him available for deposition at least one day before calling him as a witness.” ECF 121 at 19.

C. Trial

Claimants' motion for a new trial is based on two of the Court's rulings at trial: (1) the exclusion of Claimants' Trial Exhibit 261 ("Exhibit 261"); and (2) the admission of the testimony of Dr. Tom Brueggemeyer.

1. Claimants' Trial Exhibit 261

In their Amended Exhibit List, Claimants disclosed Exhibit 261, which was a partial transcript of a series of four conversations between undercover agents of the U.S. Drug Enforcement Agency ("DEA") and Mr. George. Before trial, the Government objected to Exhibit 261 on both hearsay and relevance grounds. The Court reserved ruling at the pretrial conference, but at trial, excluded Exhibit 261 under Federal Rule of Evidence ("FRE") 403. The Court explained that Exhibit 261 was "too far afield" and that by exploring Mr. George's alleged decision not to engage in illegal drug manufacturing after his earlier drug-related conviction, the trial would get "into different and unrelated issues." Trial Tr., ECF 153-2 at 5-6.

2. Trial Testimony of Dr. Brueggemeyer

Pursuant to the Court's ruling at the pretrial conference, *see* ECF 121, Claimants took Dr. Brueggemeyer's deposition on the evening of November 4, 2013, one day before his trial testimony on November 5, 2013. The next morning, counsel for Claimants confirmed that the deposition had been taken, and Claimants made no further objections on the record. Claimants also did not move for any postponement or additional time or otherwise indicate that they would need additional expert testimony because of any "surprise" from Dr. Brueggemeyer's testimony.

At trial, Dr. Brueggemeyer testified that he works for the FDA's FCC laboratory. Claimants' Ex. P, ECF 149-16 at 5. His testimony explained what the FCC is and what it does. *Id.* at 7. He generally described the number of employees, the type of work employees at the FCC perform, how samples come into the FCC, handling procedures for samples, and types of

tests that the FCC often uses in its analyses of samples. Regarding FCC testing methods, counsel for the Government asked Dr. Brueggemeyer on direct examination about the tests specifically used to analyze the Maxam product samples, the type of substances that were undetectable, and why the tests cannot detect all substances. *Id.* at 16-25. Dr. Brueggemeyer explained that the testing performed could not detect the analogues of all known controlled substances. *Id.* at 22. When asked if it was possible that the FCC might not have in its library the analogues of a common type of depressant or other drug, Dr. Brueggemeyer responded: “Yes, that is correct.” *Id.* at 22-23. Dr. Brueggemeyer’s testimony was consistent with the Government’s lay witness testimony statement. *See* ECF 92.

DISCUSSION

A. Claimants’ Objection to the Exclusion of Trial Exhibit 261

Claimants argue that the Court improperly excluded Claimants’ Trial Exhibit 261. Claimants contend that Exhibit 261, because it revealed that Mr. George refused the offer from undercover DEA agents in 2004 to manufacture illegal drugs, was integral to the proposition that Mr. Cole believed that Mr. George was no longer involved in any illegal activities and therefore did not believe it necessary to disclose Mr. George’s earlier criminal conviction when Maxam touted its “Harvard-trained biochemist” in its advertising and promotional material. Claimants also argue that if Mr. George’s 1984 federal criminal conviction for controlled substances (Trial Exhibit 2, which was received in evidence) was relevant, and which was known but not disclosed by Claimants, then Mr. George’s later refusal to continue to manufacture illegal drugs was also relevant.

The Court disagrees. Exhibit 261 is neither relevant nor is its exclusion prejudicial in this case. In addition, any probative value it may have was substantially outweighed by its risk of confusing the issues. The Government, in order to establish that Defendants are subject to

forfeiture, must show by a preponderance of the evidence that: (1) Claimants committed mail or wire fraud as part of the sale of Maxam or TurboSonic products; and (2) Defendants are, or are traceable to or derived from, proceeds of that mail or wire fraud as part of the sale of Maxam or TurboSonic products. *See* 18 U.S.C. §§ 981(a)(1)(C), 1341, 1341, 1956(c)(7), 1961(1).

The Government’s theory of liability regarding Claimants’ failure to disclose Mr. George’s criminal history and lack of qualifications to manufacture pharmaceutical drugs was just part of the Government’s broader theory of fraud—that Claimants engaged in a deliberate plan of action or course of conduct by which they intended to deceive or cheat the public. The Government argued at trial that failing to disclose Mr. George’s criminal conviction and lack of scientific qualifications were only two of numerous material omissions and misrepresentations.

The Court finds that Mr. Cole’s basis for his belief that Mr. George was a “reformed felon” is irrelevant to the facts at issue in this case.² Mr. Cole did not disclose in Maxam advertising that Mr. George was a convicted felon, lacked scientific training, and had made false statements about his own training and connections with Harvard University. Mr. Cole also admitted at trial that Mr. George’s manufacturing processes were both unverified and not in compliance with the processes that Maxam described to the general public as part of the sale of Maxam supplements. In this case, it was Claimants’ actions, misrepresentations, and material omissions that established fraud, not the tangential issue of whether Mr. George had abstained from committing further crimes after his previous conviction.

² Mr. Cole was not precluded at trial from stating that he believed Mr. George was a reformed felon. In fact, Mr. Cole testified that his decision to hire Mr. George is consistent with Mr. Cole’s past practice of hiring former felons to work at a gym he owned and managed in Hood River, Oregon. Mr. Cole explained that he did not believe that a prior conviction should necessarily preclude someone from employment.

Claimants also argue that Exhibit 261 should have been admitted as nonhearsay under FRE 801(c) because Claimants offered Exhibit 261 “to show the effect on the listener,” specifically that Mr. Cole had knowledge that Mr. George chose not to manufacture illegal drugs in 2004. *See* Claimants’ Reply, ECF 154 at 12 (quoting *United States v. Diaz-Arismendi*, 1994 WL 198629, at *2 (9th Cir. May 19, 1994)); FRE 803(3). Even if not offered for the truth of the matter asserted, the Court continues to find that Exhibit 261 was properly excluded under FRE 403; *see* Trial Tr., ECF 153-2 at 5-6. The Government’s point on this issue was not that Mr. George was actively creating illegal drugs that were put in Maxam supplements but, rather, that Mr. Cole knew, but failed to disclose, that the Maxam supplements were manufactured in *unknown conditions* by a convicted felon, Mr. George, who lied about his academic credentials. The Government cabined the issues at trial related to Mr. George to this theory. Moreover, Mr. George’s own testimony at trial was limited to identifying who he was because he then invoked his Fifth Amendment right against self-incrimination.

Pursuant to FRE 403, the “court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” The Court continues to find that Mr. George’s decision in 2004 to decline to continue to manufacture illegal drugs went beyond simply rebutting the Government’s actual theory of fraud and, instead, risked confusing the issues at trial and misleading the jury. *Id.*

Further, the jury’s verdict was not contrary to the clear weight of the evidence. *See Murphy*, 914 F.2d at 187. The clear weight of the evidence at trial indicated that Mr. Cole had not inspected the manufacturing processes that Mr. George used to make the components of the Maxam supplements. *See Passantino*, 212 F.3d at 510 n.15. Despite Mr. Cole’s testimony

regarding his belief in many of Mr. George's representations, the Government provided compelling evidence that Mr. George's representations regarding his training and professional affiliations were untruthful, and there was sufficient evidence to conclude that Mr. Cole was aware of these misrepresentations. The clear weight of the evidence does not conflict with the jury's verdict, and as a result, granting Claimants a new trial would not serve the interests of justice. *See Roy*, 896 F.2d at 1176.

B. Claimants' Objection to the Testimony of Dr. Tom Brueggemeyer

Claimants also object to the testimony of Dr. Tom Brueggemeyer and contend that Dr. Brueggemeyer's testimony failed to comply with Federal Rules of Civil Procedure 26(a)(2) ("Rule 26(a)(2)") and (b)(4) ("Rule 26(b)(4)"). Claimants argue that Dr. Brueggemeyer provided expert testimony under FRE 702 and should have been required to comply with the disclosure obligations under Rule 26(a)(2), and that the Government did not provide Claimants with an opportunity to depose Dr. Brueggemeyer under Rule 26(b)(4). The Government responds that Dr. Brueggemeyer testified as a fact witness, not as an expert, and therefore was not required to comply with the obligations of Rules 26(a)(2) and (b)(4).

The crux of Claimants' argument is that they were prevented from forming an effective response to Dr. Brueggemeyer's statement that the FDA's FCC testing would not detect all known analogues of drugs such as MDMA ("ecstasy"). In support, Claimants provide the post-trial declaration of Dr. Gregory Dudley as evidence that the statement that the FCC could only find some substances is not the "end of any fair analysis of the question of whether or not there are any accepted methods by which the presence of analogues of MDMA (or analogues of many other well-identified controlled substances) can be ruled in or ruled out." Claimants' Ex. R, ECF 149-18 at 4.

FRE 701 provides that if “a witness is not testifying as an expert, testimony in the form of opinion is limited to one that is: (a) rationally based on the witness’s perception; (b) helpful to clearly understanding the witness’s testimony or to determining a fact in issue; and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.” The purpose of clause (c) is to ensure that “a party will not evade the expert witness disclosure requirements set forth in [Rule] 26 . . . by simply calling an expert witness in the guise of a layperson.” FRE 701, Advisory Committee Notes (2000 Amendments). The distinction between lay and expert testimony is that the former is based on personal knowledge rather than scientific, technical, or other specialized knowledge. *Id.* The Federal Rules of Evidence contemplate that an individual witness may provide both expert and lay testimony. *Id.* (“Certainly it is possible for the same witness to provide both lay and expert testimony in a single case.”).

There are portions of Dr. Brueggemeyer’s testimony that fall within the providence of FRE 701, for example, his direct observation and experience in creating Trial Exhibits 11, 12, 13, 14, 15, and 16. Claimants’ Ex. P, ECF 149-16 at 27-39. Other aspects of his testimony, such as his explanation of the notations within the relevant exhibits, may fall or at least come close to falling within the category of expert testimony because they are based, at least in part, on his scientific knowledge. *See* FRE 701(c).

Claimants specifically cite to Dr. Brueggemeyer’s trial testimony in response to the following question asked by the Government during its direct examination:

Q: So is it possible then that you might have a substance in the library that is the most common type of a depressant or other drug but then not have analogues in the library?

A: Yes, that is correct. There are—there is a lot of effort going on among people who are criminally producing drugs to produce drugs that have the same effect as the original, as a cocaine or a heroin or whatever, but which are not yet scheduled. So by making small modifications, they hope to come up with a drug with similar

characteristics but might let them avoid from prosecution by saying this is not the same drug.

Claimants' Ex. P, ECF 149-16 at 22-23.

Claimants argue that this testimony was “expert testimony” under FRE 702 because Dr. Brueggemeyer confirmed the scientific limits of the gas chromatography with mass spectrometric detection analysis (“GC-MS”) that the FCC performed on certain Maxam samples. Dr. Brueggemeyer explained at trial that in conducting a GC-MS test, samples are dissolved in a solvent, injected into the GC-MS instrument, vaporized, and then moved by helium gas into a long, thin column where the components of the sample separate from each other. After leaving these columns, Dr. Brueggemeyer explained the sample components are fragmented and ionized, and based on the pattern of the fragmented sample, a testing analyst can identify molecules within the sample by comparing them to libraries of previously analyzed compounds. Dr. Brueggemeyer noted that GC-MS testing is not able to detect everything in a sample because the available libraries do not contain all analogues to previously analyzed compounds.

Claimants cite to *Rodriguez v. General Dynamics Armament and Technical Products* for the proposition that “any part of a witness’ testimony that is based upon scientific, technical, or other specialized knowledge” is within the scope of FRE 702, even if a that information relates to the witness’ job. 510 F. App’x 675, 676 (9th Cir. 2013). In *Rodriguez*, the court held that the witness’ testimony was improperly admitted and was not harmless error because that witness was the party’s “only witness at trial” and “more likely than not impacted the verdict.” *Id.* Further, the court found that the opposing party was not on notice of the testimony and was unable to prepare accordingly under “the important protections” afforded under Rule 26(a)(2).

Dr. Brueggemeyer opined that it was possible that analogues to known substances exist and are not in the GC-MS library. This testimony may well have been based on his “specialized

knowledge” rather than merely on his perceptions if it was not clear from the FCC testing results that GC-MS does not detect all known analogues. *See United States v. Figueroa-Lopez*, 125 F.3d 1241, 1246 (9th Cir. 1997). Even if a portion of Dr. Brueggemeyer’s testimony was based on his specialized knowledge, however, the Court declines to grant Claimants’ motion for two reasons. First, admitting Dr. Brueggemeyer’s testimony at most constituted harmless error. *Id.* at 1245-47. Second, the jury’s verdict was not against the clear weight of the evidence. *See Molski*, 481 F.3d at 729; *Figueroa-Lopez*, 125 F.3d at 1246-47.

1. Harmless Error

There are two aspects to this Court’s inquiry for harmless error. *See Figueroa-Lopez*, 125 F.3d at 1246-47. First, the Court evaluates whether Dr. Brueggemeyer would have been permitted to testify under FRE 702. *Id.* Second, the Court evaluates whether Claimants suffered unfair prejudice. *Id.*

a. Expert Testimony under FRE 702

The Court finds that Dr. Brueggemeyer would have been permitted to testify under FRE 702. That rule provides that expert opinion evidence is admissible if: (1) the witness is sufficiently qualified as an expert by knowledge, skill, experience, training, or education; (2) the scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (3) the testimony is based on sufficient facts or data; (4) the testimony is the product of reliable principles and methods; and (5) the expert has reliably applied the relevant principles and methods to the facts of the case. FRE 702.

Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny, a district court’s inquiry into admissibility is a flexible one. *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013). In evaluating proffered expert testimony, the trial court is “a gatekeeper, not a fact finder.” *Primiano v. Cook*, 598 F.3d 558,

565 (9th Cir. 2010) (citation and quotation marks omitted). “The trial court must assure that the expert testimony ‘both rests on a reliable foundation and is relevant to the task at hand.’” *Id.* at 564 (quoting *Daubert*, 509 U.S. at 597).

Dr. Brueggemeyer’s testimony was relevant because his knowledge had a “valid connection to the pertinent inquiry.” *See id.* at 565. His knowledge of chemistry and the GC-MS testing procedures were directly related to understanding the Government’s evidence relating to the FDA testing of Maxam supplements. Dr. Brueggemeyer’s testimony also rested on a reliable foundation. *Id.* At trial, Dr. Brueggemeyer demonstrated that he is a highly qualified chemist and explained that he had years of experience working at the FCC. Claimants’ Ex. P, ECF 149-16 at 5-7. Moreover, Dr. Brueggemeyer stated that the FCC follows set protocols that are subject to inspection by a nationally accredited organization, that GC-MS and other testing techniques were consistent with these set protocols, and that the FCC followed set methods in testing the relevant samples. *Id.* at 7-27. Moreover, Dr. Brueggemeyer’s testimony was wholly consistent with the Government’s retained testifying experts, Dr. Cory Hilmas and Dr. Robert Temple, and added nothing “new” beyond a first-hand factual account of the FCC’s test results for the Maxam supplements. *See* Temple Report, ECF 93-1; Hilmas Report, ECF 93-3; *cf. Rodriguez*, 510 F. App’x at 676. The Court is not persuaded that Dr. Brueggemeyer offered “unreliable nonsense opinions” that the Court should have screened from the jury. *See Alaska Rent-A-Car*, 738 F.3d at 969.

b. Unfair Prejudice

Regarding the issue of unfair prejudice, the Court notes that the Government’s disclosures have been both consistent and complete regarding the: (1) allegations of fraud; and (2) disclosure of Dr. Brueggemeyer’s testimony. Moreover, the relevant substantive aspects of Dr. Brueggemeyer’s testimony challenged by Claimants are fully corroborated by other properly

PAGE 17 – OPINION AND ORDER

admitted evidence about which there was no objection. *Cf. Rodriguez*, 510 F. App'x at 676. As previously explained, based on the deposition of Dr. Thompson from J-Star and Mr. Cole, the Government revised its theories of fraud. The Government's revised theories related to Mr. George's use of custom-made compounds from J-Star, which included MAOIs, SSRIs, a prescription drug that metabolizes in the body to methamphetamine, and an analogue to ecstasy, and the fact that Mr. George was a convicted felon that lacked the qualifications Maxam advertised to the public. Pl.'s Supp. Resp., ECF 153-1 at 3-5.

Claimants maintain that the Government did not fully disclose its theory before trial that the FCC's inability to detect analogue drugs meant that there was a possibility that Maxam supplements could contain trace amounts of these substances. Claimants, however, do not explain how Dr. Hilmas's expert report failed to put Claimants on notice of this theory.

Dr. Hilmas's expert report and subsequent trial testimony, to which there was no objection, spelled out the theory of fraud to which Claimants object in connection with Dr. Brueggemeyer's testimony—that the analogue drugs ordered from J-Star tainted the Maxam supplements, even if they were not detected by the FCC. *See* Claimants' Ex. I, ECF 149-9 at 2. Dr. Hilmas's report explained that J-Star “compounds synthesized for Maxam at the request of Dan George . . . includes a number of aliphatic amines . . . including prescription Monoamine Oxidase Inhibitors (MAOIs), prescription Selective Serotonin Reuptake Inhibitors (SSRIs), a drug used for Parkinson's disease, analogs [*sic*] of the above, and a substance with a chemical structure similar to MDMA or ecstasy.” *Id.* at 6. Dr. Hilmas opined that if J-Star compounds are used in the manufacturing process, they would be “included in the final Maxam product, likely at very low levels that are below the detection limit of the screening methods FDA used in their analysis of the products.” *Id.* at 8. Although Dr. Hilmas concluded that it is “likely that there

would not be any pharmacological effect” of the J-Star compounds in the Maxam supplements, any such existing effects “would have been constantly changing because the identity of the compounds J-Star created for Maxam were constantly changing over the years.” *Id.* After receiving Dr. Hilmas’s expert report, Claimants did not request an extension of the trial date to identify an expert to challenge Dr. Hilmas’s proposed testimony, even though Claimants explained in a status conference that they had contemplated doing so. *See* ECF 89, 90.

Second, the Government fully and timely disclosed to Claimants the nature of Dr. Brueggemeyer’s testimony. As explained in the Government’s response to Claimant’s pretrial objection, Claimants have consistently had the opportunity to learn about FCC testing, and that although Dr. Jennifer Brzezinski, an employee at the FCC that tested the Maxam samples, could not identify in her deposition testimony the detection limits of the FCC’s testing techniques, her supervisor Dr. Brueggemeyer had that information. Claimants’ Designation of Dep. Test., ECF 107-1 at 10, 13, 22, 24-25, 40. Moreover, Dr. Brueggemeyer’s trial testimony did not stray from his lay witness testimony statement disclosed by the Government. *See* Claimants’ Ex. P, ECF 149-16. The testimony provided by Dr. Brueggemeyer was also consistent with the testimony of Dr. Hilmas. *See* Claimants’ Ex. I, ECF 149-9.

In addition, Claimants were aware that Mr. George’s past conviction and the lack of verifiable laboratory conditions were part of the Government’s case-in-chief. With all of these facts known, there is no reason that Claimants could not have retained Dr. Dudley in anticipation of trial to present the theory that Claimants now raise in their pending motion: that the Government has not shown there were drugs present in the Maxam supplements. Further, the significant hurdle that Claimants face in relying on Dr. Dudley’s proposed testimony is that his expert opinion would not refute the Government’s theory and evidence that Claimants’ failure to

disclose Mr. George's actual credentials and the actual manufacturing processes for Maxam supplements was fraudulent.

Thus, even if a portion of Dr. Brueggemeyer's testimony were subject to Rule 26(a)(2), Claimants were aware of the FCC employees involved in this case, including Dr. Brueggemeyer, and all the relevant facts well before trial and did not any postponement or delay in order to retain an expert. *See* ECF 90; Fed. R. Civ. P. 26(a)(2)(D)(i). Further, Claimants have not argued that Dr. Brueggemeyer would not qualify as an expert under FRE 702. Thus, the lack of a FRE 702 hearing or the notice required under Rule 26(a)(2) did not prejudice Claimants. *See Figueroa-Lopez*, 125 F.3d at 1245. The Court finds that the admission of Dr. Brueggemeyer's testimony was, at most, harmless error to the extent it may have strayed beyond that of a lay witness.

2. Weight of the evidence

The second basis by which the Court could grant a new trial under Rule 59(a) is if the "verdict is against the weight of the evidence." *Molski*, 481 F.3d at 729. Claimants' motion operates under the assumption that Claimants lost at trial because of the Government's focus on the potential presence of drugs in the Maxam supplements. *See* ECF 149 at 24-25. Claimants argue that the sole basis for the Government's focus on this theory in its closing argument is the testimony of Dr. Brueggemeyer.

In addition to Dr. Brueggemeyer's testimony, however, Dr. Hilmas provided in his expert report:

If Dan George is using the JStar compounds in the Maxam manufacturing process, then the JStar compounds used in the broth are included in the final Maxam product, likely at very low levels that are below the detection limit of the screening methods FDA used in their analysis of the products.

Pl.’s Attachment C, ECF 93-3 at 7. At trial, Dr. Hilmas testimony directly addressed his analysis of the FCC test results. Pl.’s Ex. 4, ECF 153-4 at 4-5; *see also* Claimants’ Ex. A, ECF 149-1 at 13 (Government’s summary of Dr. Hilmas’s testimony). The Government also presented evidence that Mr. George’s manufacturing processes were unknown and unverified and that he had received J-Star compounds that could be used to create controlled substances. Contrary to Claimants’ primary argument in the pending motion for a new trial, there were various sources of evidence that indicated that the Maxam supplements might contain undisclosed controlled substances.

Beyond this challenged theory, the Government presented evidence at trial of the following additional theories that would support a finding of mail or wire fraud:

- Maxam advertised that it made its supplements using only 100 percent natural, organic, vegan ingredients, and as not containing any herbs, vitamins, soy or other ingredients that may cause adverse reactions or imbalances in some people, when in fact the products contained bacteria not listed on the label.
- Maxam advertised that it made its supplements in a state of the art laboratory, when in fact they were handled at Maxam offices without good manufacturing practices, and in the same room where employees stored and ate food and walked through the laboratory without any health-related protocols.
- Mr. Cole falsely represented himself to be a naturopathic doctor, when in fact he is not.
- Maxam made unproven claims about the health benefits of the supplements’ use, including claims that the supplements have the ability to treat, prevent, mitigate, and improve diseases or medical conditions that have no known cure, such as autism, multiple sclerosis, and cancer.
- Claimants made misleading use of the term “Rx” in the name of many of the Maxam supplements. The term “Rx” is commonly understood to refer to prescription medications, which Maxam supplements are not.

- Claimants provided medical-sounding treatment protocols that recommended customers forego traditional medical treatments, even though no one affiliated with Maxam had any medical training.
- Claimants initially represented to customers that Maxam supplements were created at Harvard Medical Center, which was false. Even after Harvard University sent Claimants a cease and desist letter, Claimants continued to represent to customers that their recommended “protocols” for use of the Maxam supplements were developed by a Harvard biochemist. These references were a misleading reference to Mr. George, whose only connection to Harvard was a library card.

Pl.’s Trial Br., ECF 91 at 13-14.

The Government offered 102 exhibits at trial and numerous witnesses to support the contentions outlined above. Any of these additional theories of fraud could support forfeiture of Defendants. Because the Court may “weigh the evidence as [the court] saw it,” *Murphy*, 914 F.2d at 187 (citation omitted), the Court makes note of one of the several Government theories that was particularly persuasive. To support forfeiture, the Government argued that Claimants made “unproven claims about the health benefits of [the Maxam products’] use.” Pl.’s Trial Br., ECF 91 at 14. The testimony of Dr. Hilmas, Dr. Temple, Mr. Cole’s former business partner Caroline Stites, and the employees at Maxam indicated that there was no verifiable scientific evidence supporting the claim that Maxam supplements could treat a particular disease, such as autism, multiple sclerosis, or cancer. Claimants’ “satisfied customer” witnesses explained at trial that they were desperate for any treatment that could address the serious illnesses that they or a family member faced. Testimony and other evidence at trial also established that Maxam employees, despite having no medical training, developed medical “protocols” for the administration of the Maxam supplements that allegedly would treat a variety of serious illnesses.

The Court finds that the preponderance of this evidence shows that Claimants committed mail or wire fraud as part of the sale of Maxam supplements and that Defendants are, or are traceable to or derived from, proceeds of mail or wire fraud as part of the sale of Maxam supplements. *See* Court's Instructions to the Jury, ECF 129; *see also* 18 U.S.C. §§ 981(a)(1)(C), 1341, 1341, 1956(c)(7), 1961(1). The Court also finds that the jury's verdict was not against the clear weight of the evidence because Dr. Brueggemeyer's testimony was fully disclosed before trial, was substantiated by other properly received evidence at trial, and was not the sole basis for finding Defendants subject to forfeiture.

CONCLUSION

The exclusion of Trial Exhibit 261 and the inclusion of Dr. Brueggemeyer's trial testimony did not result in a fundamentally unfair trial, and the jury's verdict was not against the clear weight of the evidence. The Court DENIES Claimants' motion for a new trial. ECF 148.

IT IS SO ORDERED.

DATED this 12th day of May, 2014.

/s/ Michael H. Simon
Michael H. Simon
United States District Judge